

SUBCHAPTER K—HEALTH RESOURCES DEVELOPMENT

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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AUTHORITY: Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8 and 1395hh); and section 301 of the National Organ Transplant Act, as amended (42 U.S.C. 274e).

SOURCE: 63 FR 16332, Apr. 2, 1998, unless otherwise noted.

§ 121.1 Applicability.

(a) The provisions of this part, with the exception of § 121.13, apply to the operation of the Organ Procurement and Transplantation Network (OPTN) and to the Scientific Registry.

(b) The provisions of § 121.13 apply to the prohibition set forth in section 301 of the National Organ Transplant Act, as amended.

(c) In accordance with section 1138 of the Social Security Act, hospitals in which organ transplants are performed and which participate in the programs under titles XVIII or XIX of the Social Security Act, and organ procurement organizations designated under section 1138(b) of the Social Security Act, are subject to the requirements of this part.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56658, Oct. 20, 1999; 72 FR 10618, Mar. 9, 2007]

§ 121.2 Definitions.

As used in this part—

Act means the Public Health Service Act, as amended.

Designated transplant program means a transplant program that has been found to meet the requirements of § 121.9.

Family member means a family member of a transplant candidate, transplant recipient, or organ donor.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ means a human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or vascularized composite allograft (defined in this section). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled “For use in organ transplantation only.”

Organ donor means a human being who is the source of an organ for transplantation into another human being.

Organ procurement organization or *OPO* means an entity so designated by the Secretary under section 1138(b) of the Social Security Act.

Organ procurement and transplantation network or *OPTN* means the network established pursuant to section 372 of the Act.

Potential transplant recipient or *potential recipient* means a transplant candidate who has been ranked by the OPTN computer match program as the person to whom an organ from a specific cadaveric organ donor is to be offered.

Scientific Registry means the registry of information on transplant recipients established pursuant to section 373 of the Act.